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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,895	02/16/2006	Robert L Garcea	66888-319995	6219
35657 7590 04/27/2009 FAEGRE & BENSON LLP PATENT DOCKETING - INTELLECTUAL PROPERTY 2200 WELLS FARGO CENTER 90 SOUTH SEVENTH STREET MINNEAPOLIS, MN 55402-3901				
EXAMINER				
SALIM, ALI REZA				
ART UNIT		PAPER NUMBER		
1648				
NOTIFICATION DATE		DELIVERY MODE		
04/27/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

e-OfficeActionHNI@faegre.com
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Office Action Summary

Application No.

10/541,895

Applicant(s)

GARCEA ET AL.

Examiner

A R. Salimi

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04/03/2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 55-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 55-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Request Continued Examination (RCE)

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(c), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/03/2009 has been entered.

Response to Amendment

This is a response to the amendment filed 04/03/2009. Claims 1-54 have been canceled. Claims 55-64 have been added and currently pending.

Please note any ground of rejection that has not been repeated is removed.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

Claims 55-64 are rejected under 35 U.S.C. 102(e) as being anticipated by Gissmann et al (US Patent no. 7,371,391 B2) for reasons of record advanced in the previous Office Action mailed 06/06/2008, and 01/16/2009. Applicants assert Gissmann fails to disclose "A complex having two polypeptide having five papillomavirus capsid L1 polypeptides or truncated papillomavirus capsid L1 polypeptides..." elements of new independent claim 55. Applicants further assert, Gissmann fails to disclose a complex having a 5:1 ratio of five papillomavirus L1

polypeptides to a second polypeptide. Applicants assert Gissmann's teaching is directed to chimeric proteins not a complex of proteins that "non-covalently" associate as in the instant case.

Applicants' argument as part of amendment filed 04/03/2009 has been considered fully, but they are not persuasive.

In Applicants own disclosure in page 7, lines 20-24 Capsomere is defined as: capsid structure....native capsomere comprises a pentamer of L1 capsid proteins. Gissmann et al also taught a capsomere which happens to be "a molecule having five papillomavirus capsid L1 polypeptide." Simply defining the word rather than naming it as capsomere, does not take away from the fact that the same product was disclosed and defined. In addition, they taught chimeric protein comprising papillomavirus L1 protein and another protein wherein the composition forms capsomere. The facts still remain that the Public prior to now claimed invention was in possession of the same invention (emphasis added). And the Public should not be burdened with providing yet another right to exclude. Additionally, under inherency doctrine where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of anticipation has been established. See, In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). Thus, the limitation of "non-covalently" has no bearing here. The claimed invention is directed to a product and the same product has already been disclosed by the above cited Patent. The rejection is respectfully maintained.

Claims 55-64 are rejected under 35 U.S.C. 102(c) as being anticipated by Wilson et al (US Patent no. 6,908,613 B2) for reasons of record advanced in the previous Office Action

mailed 06/06/2008, and 01/16/2009. Applicants assert Wilson fails to disclose "A complex having two polypeptide having five papillomavirus capsid L1 polypeptides or truncated papillomavirus capsid L1 polypeptides..." elements of new independent claim 55. Applicants further assert, Wilson fails to disclose a complex having a 5:1 ratio of five papillomavirus L1 polypeptides to a second polypeptide. Applicants assert Wilson's teaching is directed to chimeric proteins not a complex of proteins that "non-covalently" associate as in the instant case.

Applicants' argument as part of amendment filed 04/03/2009 has been considered fully, but they are not persuasive.

In Applicants own disclosure in page 7, lines 20-24 Capsomere is defined as: capsid structure....native capsomere comprises a pentamer of L1 capsid proteins. Wilson et al also taught a capsomere which happens to be "a molecule having five papillomavirus capsid L1 polypeptide", Wilson in the bridging paragraph, see Columns 2 to 3 defined the capsomere as "pentamers of the L1 proteins", as Applicants are aware, Pentamer is five. And Wilson's definition reads on the now claimed limitation. Simply defining the word rather than naming it as capsomere, does not take away from the fact that the same product was disclosed and defined. In addition, they taught chimeric protein comprising papillomavirus L1 protein and another protein wherein the composition forms capsomere. The facts still remain that the Public prior to now claimed invention was in possession of the same invention (emphasis added). And the Public should not be burdened with providing yet another right to exclude. Additionally, under inherency doctrine where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of anticipation has been established. See, In re Best, 562 F.2d 1252,

1255, 195 USPQ 430, 433 (CCPA 1977). Thus, the limitation of “non-covalently” has no bearing here. The claimed invention is directed to a product and the same product has already been disclosed by the above cited Patent. The rejection is respectfully maintained.

Claims 55-64 are rejected under 35 U.S.C. 102(e) as being anticipated by Hallek et al (US Patent no. 7,182,947 B2) for reasons of record advanced in the previous Office Action mailed 06/06/2008, and 01/16/2009. Applicants assert Hallek fails to disclose "A complex having two polypeptide having five papillomavirus capsid L1 polypeptides or truncated papillomavirus capsid L1 polypeptides..." elements of new independent claim 55. Applicants further assert, Hallek fails to disclose a complex having a 5:1 ratio of five papillomavirus L1 polypeptides to a second polypeptide.

Applicants' argument as part of amendment filed 04/03/2009 has been considered fully, but they are not persuasive.

In Applicants own disclosure in page 7, lines 20-24 Capsomere is defined as: capsid structure.....native capsomere comprises a pentamer of L1 capsid proteins. Hallek et al also taught a capsomere which happens to be "a molecule having five papillomavirus capsid L1 polypeptide", and it's a term of art when a pentamer comprises five L1 capsid polypeptides. Simply defining the word rather than naming it as capsomere, does not take away from the fact that the same product was disclosed and defined. In addition, they taught chimeric protein comprising papillomavirus L1 protein and another protein wherein the composition forms capsomere. The facts still remain that the Public prior to now claimed invention was in possession of the same invention (emphasis added). And the Public should not be burdened with

providing yet another right to exclude. Additionally, under inherency doctrine where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of anticipation has been established. See, In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). Thus, the limitation of "non-covalently" has no bearing here. The claimed invention is directed to a product and the same product has already been disclosed by the above cited Patent. The rejection is respectfully maintained.

Claim Rejections - 35 USC § 102

Claims 55-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Gissmann et al (US Patent no. 6,228,368 B1) for reasons of record advanced in the previous Office Action mailed 06/06/2008, and 01/16/2009. Applicants assert Gissmann fails to disclose "A complex having two polypeptide having five papillomavirus capsid L1 polypeptides or truncated papillomavirus capsid L1 polypeptides..." elements of new independent claim 55. Applicants further assert, Gissmann fails to disclose a complex having a 5:1 ratio of five papillomavirus L1 polypeptides to a second polypeptide. Applicants assert Gissmann's teaching is directed to chimeric proteins not a complex of proteins that "non-covalently" associate as in the instant case.

Applicants' argument as part of amendment filed 04/03/2009 has been considered fully, but they are not persuasive.

In Applicants own disclosure in page 7, lines 20-24 Capsomere is defined as: capsid structure.....native capsomere comprises a pentamer of L1 capsid proteins. Gissmann et al also

taught a capsomere which happens to be "a molecule having five papillomavirus capsid L1 polypeptide." Simply defining the word rather than naming it as capsomere, does not take away from the fact that the same product was disclosed and defined. In addition, they taught chimeric protein comprising papillomavirus L1 protein and another protein wherein the composition forms capsomere. The facts still remain that the Public prior to now claimed invention was in possession of the same invention (emphasis added). And the Public should not be burdened with providing yet another right to exclude. Additionally, under inherency doctrine where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of anticipation has been established. See, In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). Thus, the limitation of "non-covalently" has no bearing here. The claimed invention is directed to a product and the same product has already been disclosed by the above cited Patent. The rejection is respectfully maintained.

Claims 55-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Garcea et al (US Patent no. 6,165,471 A) for reasons of record advanced in the previous Office Action mailed 06/06/2008, and 01/16/2009. Applicants assert Garcea fails to disclose "A complex having two polypeptide having five papillomavirus capsid L1 polypeptides or truncated papillomavirus capsid L1 polypeptides..." elements of new independent claim 55. Applicants further assert, Garcea fails to disclose a complex having a 5:1 ratio of five papillomavirus L1 polypeptides to a second polypeptide.

Applicants' argument as part of amendment filed 04/03/2009 has been considered fully, but they are not persuasive.

In Applicants own disclosure in page 7, lines 20-24 Capsomere is defined as: capsid structure....native capsomere comprises a pentamer of L1 capsid proteins. Garcea et al also taught a capsomere which happens to be "a molecule having five papillomavirus capsid L1 polypeptide." Simply defining the word rather than naming it as capsomere, does not take away from the fact that the same product was disclosed and defined. In addition, they taught chimeric protein comprising papillomavirus L1 protein and another protein wherein the composition forms capsomere. The facts still remain that the Public prior to now claimed invention was in possession of the same invention (emphasis added). And the Public should not be burdened with providing yet another right to exclude. Additionally, under inherency doctrine where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of anticipation has been established. See, In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). Thus, the limitation of "non-covalently" has no bearing here. The claimed invention is directed to a product and the same product has already been disclosed by the above cited Patent. The rejection is respectfully maintained.

New Grounds of rejection:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 55-64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 55 and 59 are confusing. These claims appear to be essential duplicates of one another. Claim 55 in-long-hand defines a penatmer molecule which is the same as capsomere, according to Applicants' own disclosure, see disclosure in page 7. Then claim 59, indicates the complex forms a "capsomere", well claim 55 is capsomere, isn't it? What is the difference between claim 55 and 59? This affects dependent claims.

Claims 55, 61 and 62 are vague and indefinite, because of the limitation "truncated", the claims have been interpreted in light of specification and the disclosure fails to teach the intended metes and bounds of the said truncation. What are the truncations that still allow the formation of a capsomere? Nothing is taught in the specification, except a wish list regarding these truncated polypeptides. Please clarify. This affects dependent claims.

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. The Official fax number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/A R Salimi/

Primary Examiner, Art Unit 1648

04/23/2009